UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,795	08/19/2003	Frederic J. DeSauvage	P5026R1	6007

9157 7590 02/20/2007

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
YAO, LEI	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,795	DESAUVAGE ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/11/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-18* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Argument and Amendment

The Amendment filed on 12/11/06 in response to the previous Non-Final Office Action (10/11/06) is acknowledged and has been entered.

Claims 1-15 have been cancelled previously. Claims 16-18 are pending. Claim 18 has been withdrawn previously for non-elected invention. Claims 16-17 are under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

Response to Arguments

Rejection under 35 USC § 102

Claims 16-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al., and 102(a) and 102 (e) as being anticipated by Gish et al., as stated below.

1. Claims 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al., (US Patent, 6262245, Date of Patent, 7/17/01) as evidenced by sequence search (exhibit A).

Xu et al., disclose a method of diagnosing a prostate tumor by determining the levels of prostate tumor related gene expressions in a prostate tumor tissue by RT-PCR comprising the expression of a nucleic acid encoding a polypeptide, which is 100% identical to the amino acid residues at 766-1085 of SEQ ID NO: 123 (see sequence search exhibit A; column 14 and 17, line 37-42, SEQ ID NO: 109, cDNA clone J1-17). Xu et al., disclose that, for PCR, the oligonucleotide primers/probe having at least 15 contiguous nucleotide of DNA selectively from the gene (SEQ ID NO:109) is employed in a prostate tumor sample and hybridized to cDNA derived from the samples (col 14-15). Xu et al., also disclose an example of determining the levels of mRNA expression in the prostate tumor tissues compared to normal prostate tissues by RT-PCR and a result indicating that the gene expression (J1-17) is significantly elevated in the prostate tissues (col 19, example 2).

Since claimed method is not drawn to a specific oligonucleotide as primers or a probe for RT-PCR for determining the expression of a gene encoding a protein shown as SEQ ID NO: 123 and since the method disclosed by Xu et al., using the same method steps and the primers having any 15 oligonucleotide from the same sequences as claimed, method disclosed by Xu et al., anticipates the claimed method of diagnosing the presence of a prostate tumor by determining the levels of expression of a gene encoding a polypeptide shown as SEQ ID NO: 123 by RT-PCR.

2. Claims 16-17 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by Gish et al., (WO 02/30268, published date 4/18/02, and effective filing date, 10/13/ 2000) as evidenced by sequence search (exhibit B).

Gish et al., disclose a method of diagnosing a prostate cancer by detecting a prostate cancer-associated transcript (mRNA) in a cell from a patient comprising determining a nucleic acid encoding a polypeptide, which is 99.6% identical to the amino acid sequence of SEQ ID NO: 123, different at first 4 amino acids (see sequence search, exhibit B; page 322-323 and 139, protein sequence, SEQ ID NO: 53 having accession no: AA431407; page 339-340, corresponding DNA sequence, SEQ ID NO:105). Gish et al., disclose the method comprising contacting a biological sample from a prostate patient with a polynucleotide probe that selectively hybridizes to the sequence (page 3). Gish et al., further disclose that the nucleic acid comprising mRNA expressed in prostate cancer sample is detected by *in situ* hybridization or PCR (page 59, 61, and 91-97, example 1). Gish et al., also disclose that expressing the specific prostate cancer gene in the prostate tumor tissue (accession no: AA431407) is up-regulated compared to the normal prostate tissue (Table 4, page 139, line 3).

Since claimed method is not drawn to a specific oligonucleotide as primers or a probe for the in situ hybridization or RT-PCR, the method disclosed by Gish et al., anticipates the claimed method of diagnosing the presence of a prostate tumor comprising determining the levels of expression of a gene encoding the polypeptide shown as SEQ IDNO: 123 by an in situ hybridization or RT-PCR.

The response filed 12/11/06 has been carefully considered but is deemed not to be persuasive. The response argues *that Xu et al., does not teach the necessary step of claimed method explicitly "determining the levels of expression of a gene encoding the polypeptide shown as SEQ ID NO: 123". In particular, the references do not teach the same amino acids that disclosed in the present application as SEQ ID NO:123 and as such, the references do not teach the step of measuring the expression of a gene that encodes a polypeptide having that amino acid sequence.* In response to this argument, first, the Office agrees, the entire coding sequence of the DNA for the polypeptide of SEQ ID NO: 123 is not disclosed by either Xu et al., or Gish et al. Xu et al., disclose a DNA encoding the polypeptide 766-1085 of SEQ ID NO: 123 and Gish et al. disclosed a DNA encoding the polypeptide 5-1127 of SEQ ID NO:123 (3 amino acid different at N-terminal). However, the instant claims are directed to a method of diagnosing a prostate tumor by determining the levels of expressing the gene by employing an oligonucleotide and the sequence of oligonucleotide as a primer or a probe is not specifically recited in the claims. Because the DNA encoding the protein of SEQ ID NO:123 comprises the DNA disclosed by both Xu et al., and Gish et al., the oligonucleotide as primer or as a probe could amplify and/or detect the gene products of Xu et al., or Gish et al., would pick up entire and/or a part of the gene product encoding the protein of SEQ ID NO:123, which is sufficient to indicate or suggest the expression levels of the gene product in the test prostate tissues or cells. Second, both Xu et al., or Gish et al., disclose a method step of determining the levels of expressing the gene in a prostate tissues, a method step of comparing the expression levels, and a method step of higher levels of gene expression indicating the presence of prostate tumor in a mammal. Thus, the references by Xu et al., and Gish et al., disclose every element recited by the claims and teach every limitation in claims, therefore, anticipate claimed method. Accordingly, applicant's argument has not been found persuasive, and the rejection is maintained for reason of the record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600